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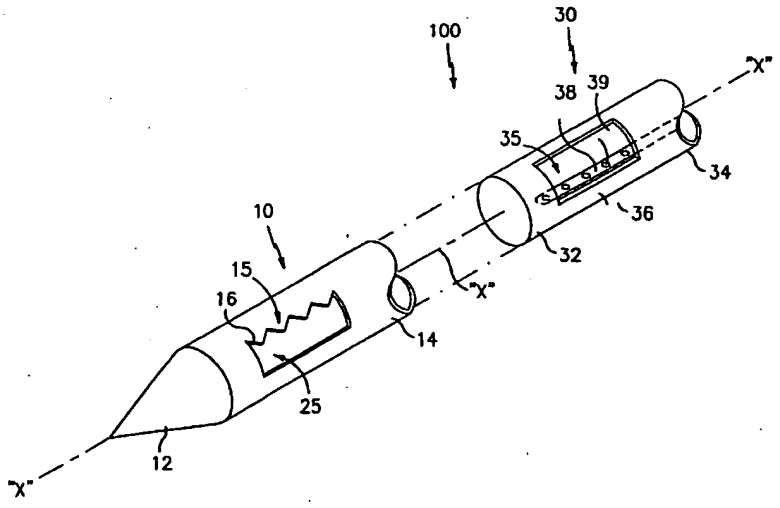
(54) Title: BIOPSY APPARATUS AND METHOD




(57) Abstract: A biopsy apparatus (100) for taking internal samples from a patient that employs a hollow needle penetrating member (10) with an integral cutter (15) and an inner member (30) for retrieving tissue samples. The penetrating member includes a needle tip, a tissue port (25), and a vacuum for assisting in severing tissue samples. The inner member contains a tissue basket for receiving at least one tissue sample and can be rotated independently of the penetrating member and removably positioned while the penetrating member remains in position in the patient. The method for the biopsy apparatus includes positioning the tissue port of the apparatus at least partially within or adjacent a tissue portion to be sampled, applying a vacuum to the tissue port and displacing the outer member to sever a tissue sample, and withdrawing the inner member proximally to transport the tissue sample through the outer member. The biopsy apparatus is capable of severing and recovering sequential tissue samples while the penetrating member remains within the patient.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# BIOPSY APPARATUS AND METHOD

## BACKGROUND

### 1. Technical Field

The present disclosure relates to instruments and methods used for obtaining tissue samples. More particularly, the present disclosure relates to minimally invasive biopsy instruments and methods for obtaining tissue samples.

### 2. Background of Related Art

It is often necessary to sample tissue in order to diagnose and treat patients suspected of having cancerous tumors, pre-malignant conditions and other diseases or disorders. Typically, in the case of suspected cancerous tissue, when the physician establishes by means of procedures such as palpation, x-ray or ultrasound imaging that suspicious conditions exist, a biopsy is performed to determine whether the cells are cancerous. Biopsy may be done by an open or percutaneous technique. Open biopsy removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy on the other hand is usually done with a needle-like instrument and may be either a fine needle aspiration (FNA) or a core biopsy. In core biopsy, as the term suggests, a core or fragment tissue is obtained for histologic examination which may be done via frozen section or paraffin section.

The type of biopsy utilized depends in large part on the circumstances present with respect to the patient and no single procedure is ideal for all cases. Core biopsy, however, is extremely useful in a number of conditions and is being used more frequently.

Intact tissue from the organ or lesion is preferred by medical personnel in order to arrive at a definitive diagnosis regarding the patient's condition. In most cases only part of the organ or lesion need be sampled. The portions of tissue extracted must be indicative of the organ or lesion as a whole. In the past, to obtain adequate tissue from organs or lesions within the body, surgery was performed so as to reliably locate, identify and remove the tissue. With present technology, medical imaging equipment such as stereotactic x-ray, fluoroscopy, computer tomography, ultrasound, nuclear medicine and magnetic resonance

imaging, may be used. These technologies make it possible to identify small abnormalities even deep within the body. However, definitive tissue characterization still requires obtaining adequate tissue samples to characterize the histology of the organ or lesion.

The introduction of stereotactic guided percutaneous breast biopsies offered alternatives to open surgical breast biopsy. With time, these guidance systems have become more accurate and easier to use. Biopsy guns were introduced for use in conjunction with these guidance systems. Accurate placement of the biopsy guns was important to obtain useful biopsy information because only one small core could be obtained per insertion at any one location. To sample the lesion thoroughly, many separate insertions of the instrument had to be made.

Biopsy procedures may benefit from larger tissue samples being taken, for example, tissue samples as large as 10 mm across. Many of the prior art devices required multiple punctures into the breast or organ in order to obtain the necessary samples. This practice is both tedious and time consuming.

One further solution to obtain a larger tissue sample is to utilize a device capable of taking multiple tissue samples with a single insertion of an instrument. Generally, such biopsy instruments extract a sample of tissue from a tissue mass by either drawing a tissue sample into a hollow needle via an external vacuum source or by severing and containing a tissue sample within a notch formed on a stylet. Such devices generally contemplate advancing a hollow needle into a tissue mass and applying a vacuum force to draw a sample into the needle and hold the same therein while the tissue is extracted.

A continuing need exists for percutaneous biopsy apparatus and methods which can reliably extract adequate biopsy sample(s) with a single insertion of the biopsy instrument.

## SUMMARY

A biopsy apparatus is provided that employs a hollow needle penetrating member with an integral cutter and a removable inner member that contains a tissue basket. A vacuum is applied at a tissue port in the needle to augment tissue sampling. The cutter is fixedly positioned in the tubular body of the needle and the needle is translated or rotated to sever tissue samples. An inner member is positioned within the hollow needle to collect and withdraw one or more tissue samples while the needle remains in position within the patient.

A biopsy method is provided wherein a biopsy apparatus, including a hollow needle penetrating member with an integral cutter and a removable inner member that contains a tissue basket, is positioned at least partially within or adjacent a suspect portion of tissue to be sampled from within a patient's body. A vacuum is applied to the tissue port and the penetrating member is displaced to sever a tissue sample. An additional tissue sample may be obtained or the inner member is withdrawn proximally to transport the at least one tissue sample through the penetrating member.

The presently disclosed biopsy apparatus, together with its attendant advantages, will be best understood by reference to the following detailed description when used in conjunction with the figures below.

## BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the presently disclosed biopsy apparatus are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of the distal end of one embodiment of a biopsy apparatus constructed in accordance with the present disclosure with a penetrating member having an integrated longitudinal cutter and an inner tube;

FIG. 2A is a perspective view of an alternate embodiment one configuration of a biopsy apparatus constructed in accordance with the present disclosure with a penetrating member having an axial cutter and a liner member; and

FIG. 2B is an axial cross section of one configuration of the biopsy apparatus constructed in accordance with the present disclosure with a penetrating member having an axial cutter and a liner member.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now in specific detail to the drawings in which like reference numerals identify similar or identical elements throughout the several views, and initially to FIG. 1, the biopsy apparatus and method with an integrated penetrating member and cutter (hereinafter referred to as "biopsy apparatus 100") includes a penetrating member 10, an inner member 30, and a vacuum source (not shown).

For purposes of clarity, only the details of the working distal ends 12 and 32 of penetrating member 10 and inner member 30, respectively, are illustrated in detail. The proximal ends may be attached to a suitable handle or actuator to facilitate operation of biopsy apparatus 100 or any of the different embodiments or configurations disclosed herein. For example, biopsy apparatus 100 may include a housing wherein outer member 10, needle 20, and inner member 30 are housed. The housing may include suitable known driving and actuating mechanisms. In one embodiment the penetrating member may be rapidly movable into position at the target tissue location by a suitable drive mechanism, such as, for example, potential energy devices, drive motors, pneumatic devices, or any other suitable drive mechanism.

Penetrating member 10 is an elongated hollow tubular needle with a distal end 12 that defines a needle tip and an opposing proximal end (not shown). For purposes of clarity, only the details of the working distal end 12 are illustrated in detail. The proximal end of penetrating member 10 may be attached to a suitable handle or actuator to facilitate operation of biopsy apparatus 100. For example, biopsy apparatus 100 may include a housing wherein penetrating member 10 and inner member 30 are housed. The housing may include suitable known driving and actuating mechanisms. In one embodiment penetrating member may be rapidly movable into position at the target tissue location by a suitable drive mechanism, such as, for example, potential energy devices, drive motors, pneumatic devices, or any other suitable drive mechanism.

Distal end 12 and the proximal end of penetrating member 10 define a central longitudinal axis "X." Penetrating member 10 also includes a tissue port 25 having an integrated cutter 15 with at least one cutting edge 16. Integrated cutter 15 is shown having both a longitudinal and a serrated edge, but it could be any suitable directional orientation, such as axial or diagonal, or any suitable geometric shape edge capable of slicing or severing a particular type of tissue sample. Penetrating member 10 is made of a medical grade material suitable for a penetrating needle.

Inner member 30 is a hollow tube that includes a distal end 32 and a proximal end (not shown) that preferably defines a central longitudinal axis coincident with axis "X." In an alternate configuration, inner member 30 is non-concentrically disposed relative to penetrating member 10. Distal end 32 includes a tissue port 35 defined by perimetral outside

walls 36. A vacuum lumen 38 is positioned opposite tissue port 35 with a plurality of through holes 39 for drawing a vacuum through basket port 35 and tissue port 25 as well as withdrawing fluids. The proximal end of inner member 30 contains a connection with a vacuum source (not shown) independent of the positioning of penetrating member 10 and inner member 30. Inner member 30 is preferably constructed of medical grade plastic or metal. Penetrating member 10 and inner member 30 are slidingly engaged such that penetrating member 10 and inner member 30 can rotate together or independently.

In operation, biopsy apparatus 100 or any of the different embodiments or configurations disclosed herein may be inserted by suitable known techniques, for example, by motor driver or spring fired mechanisms. Alternatively, biopsy apparatus 100 may be inserted manually. In either arrangement, biopsy apparatus 100 or any of the different embodiments or configurations disclosed herein may be configured as a hand held apparatus or as part of a frame mounted device. An example of such a device is an image guided positioning apparatus such as a stereotactic imaging machine. Any suitable imaging modality may be used to guide biopsy apparatus to the target tissue.

In operation, biopsy apparatus 100 is inserted in the patient at the target tissue location in a first, closed configuration wherein inner member 30 is positioned within penetrating member 10 exposing at least a portion of outside wall 36 in tissue port 25. Biopsy apparatus 100 may be inserted by suitable known techniques, for example, by motor driver or spring fired mechanisms. Alternatively, biopsy apparatus 100 may be inserted manually. In either arrangement, biopsy apparatus 100 may be configured as a hand held apparatus or as part of a frame mounted device. An example of such a device is an image guided positioning apparatus, such as a stereotactic imaging machine. Any suitable imaging modality may be used to guide biopsy apparatus to the target tissue.

Once biopsy apparatus 100 is positioned adjacent the tissue to be sampled, inner member 30 is rotated to align tissue port 35 with tissue port 25 to form an open second position and a vacuum is initiated through lumen 38 and holes 39 to assist in the drawing of tissue into tissue port 25. Either penetrating member 10 or inner member 30 are then rotated along the longitudinal axis "X" about one another to engage cutting edge 16 with the desired tissue and to sever a tissue portion. The tissue portion is retained by the vacuum within inner member 30. Penetrating member 10 can then be translated or rotated for additional samples

or inner member 30 withdrawn with the at least one tissue sample. Inner member 30 can then be re-inserted into penetrating member 10 and additional tissue samples taken. Biopsy apparatus 100 is placed in a first position, with wall 36 closing tissue port 25, for withdrawal from the patient.

Referring now to FIG. 2A, biopsy apparatus 200 includes a hollow penetrating member 210 with a cutter 215, a distal end 212 with a needle tip 213, and a proximal end (not shown). Distal end 212 and the proximal end define a central longitudinal axis "X." Cutter 215 includes a cutting edge 216 that can be formed of suitable geometric shapes such as a triangle or a semi-circle and can additionally include serrations or similar suitable features on edge 216 to enhance the cutting or gripping of tissue during cutting.

A vacuum lumen 218 is positioned in needle 210 and fluidly connected to a vacuum source (not shown). Vacuum lumen 218 defines a plurality of through holes 219 positioned opposite tissue port 225. An inner member 230 that is a liner or an insert that is independently rotatable within penetrating member 210 includes a distal end 232, a proximal end (not shown), and a tubular wall 236. Wall 236 defines a tissue port 235 on distal end 232. Distal end 232 and proximal end define a longitudinal axis concentric with penetrating member 210. Liner 230 may be constructed of a semi-rigid medical grade plastic or metal in the form of a flexible mesh or lattice that is configured to be inexpensive and disposable. Liner 230 may be removably positioned within penetrating member 210 for retrieving tissue samples. In an alternative configuration, liner 230 is made of a rigid mesh or lattice material that is slidingly positioned between vacuum lumen 218 and the inside circumference of penetrating member 210 such that member 230 is non-concentric within penetrating member 210.

In FIG. 2B, a cross section of penetrating member 210 along line 2B-2B of FIG. 2A shows penetrating member 210 with liner 230 installed in distal end 212 and ports 225, 235 aligned for tissue sampling. Wall 236 flexes around lumen 218 and the vacuum is applied through lumen 218 and holes 219, liner wall 236, tissue basket 237, and port 235 to draw tissue into port 225.

Referring now to FIGS. 2A and 2B, in operation biopsy apparatus 200 pierces the patient in a first closed configuration wherein tissue port 225 is closed by wall 236 of liner 230. Once penetrating member 210 is positioned adjacent the tissue to be sampled, liner 230

is rotated to position tissue port 235 in alignment with tissue port 225. A vacuum is then applied through lumen 218, holes 219 and wall 236 of liner 230. Penetrating member 210 is then translated proximally to sever a tissue sample. The tissue sample is retained by the vacuum in tissue basket 237. Additional tissue samples can be taken or liner 230 can then be withdrawn from the penetrating member 210 while penetrating member 210 is retained in position within the patient. A new liner 230 can then be repositioned for an additional sample or series of samples. The biopsy apparatus 200 is removed from the patient while in the first closed position.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, it is to be understood that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be affected therein by one skilled in the art without departing from the scope or spirit of the disclosure. All such changes and modifications are intended to be included within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A biopsy apparatus comprising:

a penetrating member including a distal end that defines a tissue port and a proximal end, wherein the distal end and the proximal end define a longitudinal axis and the penetrating member is rotatable about the longitudinal axis;

an integral cutter formed in the penetrating member for cutting tissue samples;

an inner member removably positioned and independently rotatable within the penetrating member, wherein the inner member defines a tissue basket for retaining at least one tissue sample therein and wherein the inner member includes a tissue port formed therein; and

a vacuum lumen positioned within the biopsy apparatus that is fluidly connected to a vacuum source and positioned to draw a vacuum through the tissue port.

2. A biopsy apparatus according to claim 1, wherein the integral cutter includes at least one cutting edge formed along at least one perimeter edge thereof.

3. A biopsy apparatus according to claim 2, wherein the cutting edge of the integral cutter is formed along at least one longitudinal edge thereof.

4. A biopsy apparatus according to claim 2, wherein the cutting edge of the integral cutter is formed along a proximal edge thereof.

5. A biopsy apparatus according to claim 2, wherein the penetrating member further comprises a vacuum lumen integrally formed along an inner surface thereof, the vacuum lumen having a plurality of holes formed along a length thereof.

6. A biopsy apparatus according to claim 5, wherein the inner member is made from an open mesh semi-rigid material.

7. A biopsy apparatus according to claim 6, wherein the vacuum lumen is in fluid communication with the tissue basket of the mesh inner member while the mesh inner member is in any radial position relative to the penetrating member.

8. A method of taking internal tissue samples with a biopsy apparatus comprising the steps of:

placing a penetrating member in a first position, wherein a tissue port is at least partially closed by an inner member, adjacent a portion of tissue to be sampled;

rotating the inner member to a second position to open the tissue port;

applying a vacuum through the tissue port;

severing at least one tissue sample from the portion of tissue to be sampled by at least one of rotating and translating the inner member relative to the penetrating member; and

placing the needle in the first position for withdrawal from the patient.

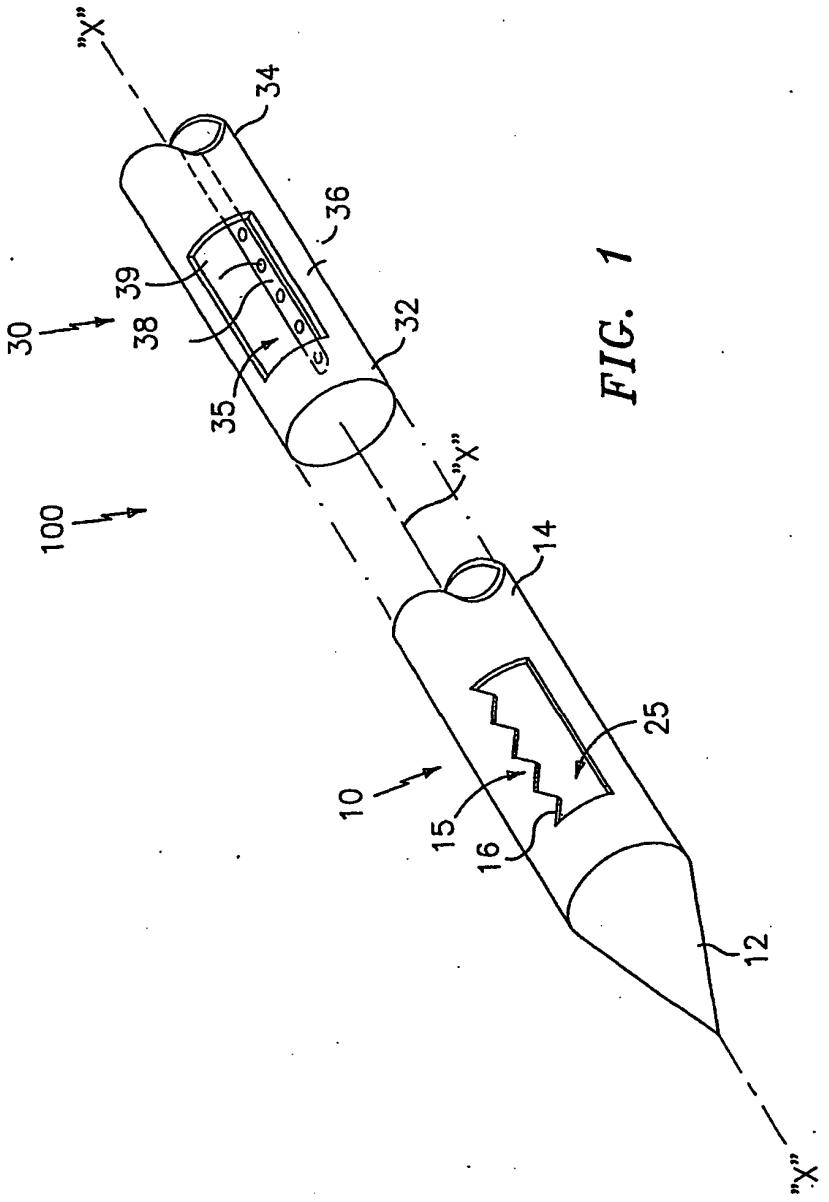
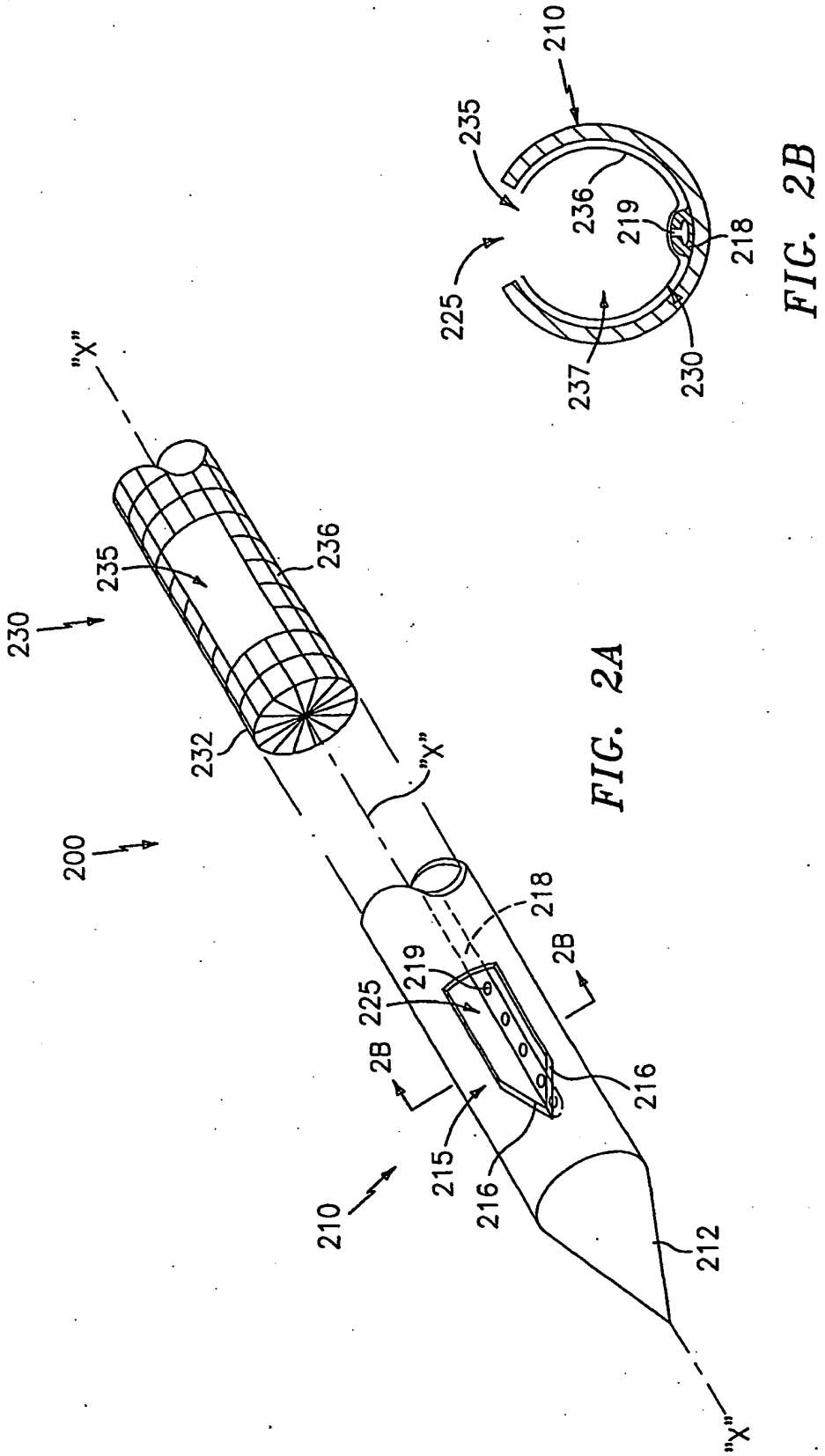



FIG. 1


"X"
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"X"
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2B
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"X"

FIG. 2A


210
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FIG. 2B

INTERNATIONAL SEARCH REPORT

Inte al Application No
PCT/US 02/02986

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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|---|---|
| 17 June 2002 | 25/06/2002 |

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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Hamann, J |

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